

National Commission for the Protection of Human Subjects
of Biomedical and Behavioral Research

Approved For Release 2005/09/28 : CIA-RDP79M00983A001500050022-4

Westwood Building, Room 125
5333 Westbard Avenue
Bethesda, Maryland 20016

August 23, 1977

Mr. Walter Elder
Executive Secretary
National Foreign Intelligence Board
Intelligence Community Staff
Washington, D.C. 20505

Dear Mr. Elder:

On June 10, 1977, the Commission reviewed revised draft "Guidelines for Human Subject Research Within the Intelligence Community" and attachments thereto which you forwarded to us for comment. Some Commission members expressed concern regarding classified research conducted or supported by the Intelligence Community, and they requested clarification from your staff before commenting on the draft. On July 8, Lt. Col. Arkadie Novickoff and Dr. Salvatore Cianci testified before the Commission, explaining the nature of research conducted or supported by the Intelligence Community and the purpose of classifying some of such research as secret. Following consideration of this testimony, as well as a review of the proposed directive, the Commission offers the following comments on the draft "Guidelines."

The revised directive is a clear improvement over the first draft (dated 16 December 1976) and reflects most of the previous comments of this Commission. We appreciate the care with which your staff has responded. Our primary remaining concern is one that cannot be disposed of within the Intelligence Community itself, but would require presidential action, at a minimum, or legislation. Specifically, the Commission is concerned with the need to provide strong assurance that human rights will be protected in classified research. The mere promulgation of a directive such as the "Guidelines" may clarify the basic policies that the various intelligence agencies are expected to follow, but carries little force or authority beyond that of exhortation. Adherence to the basic policies should be required at least by Executive Order. Preferably, deviation from such policies as are established in the "Guidelines" should be prohibited by statute. Only if such steps are taken can we be reasonably assured that the well-intentioned "Guidelines" will in fact be followed by the intelligence agencies.

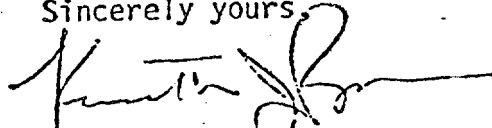
Our suggestions for specific modification of the "Guidelines" are as follows:

- (1) When sponsorship of research is not to be disclosed for security considerations, the "Guidelines" should require that subjects be informed, as part of the information provided when their consent is solicited, that the sponsor does not wish to be identified.
- (2) In the rare instances in which all aspects of a research project are classified and the research, therefore, must be reviewed by an Institutional Review Board (IRB) of which all members have security clearance, a second review of the protocol should be required. Preferably, such review would be performed by this Commission or its successor body; alternatively, it could be accomplished by the select committees in Congress having oversight of Intelligence Community operations. This would strengthen monitoring of the Intelligence Community's research activities, and, secondarily, enhance public confidence.
- (3) The duties of the "resident expert," as described in Section 5(b), should be expanded to include review of the composition and operations of IRBs reviewing Intelligence Community research, when such IRBs do not have approved assurances on file with DHEW. In addition, the "resident expert" should be designated, at least for intramural research, as a person to be contacted by subjects in the event of adverse effects attributable to participation in research.
- (4) The "Guidelines" should require the maintenance by appropriate authorities of records identifying subjects of drug research or other research presenting risk of harm that may not become known until after the research has been conducted. This would enable subjects to be contacted for follow-up examinations and would facilitate corroboration of claims of research-related injury.

We appreciate your openness and cooperation in developing this directive and your sensitivity to the problems of protecting human subjects. The "Guidelines" are, with the few exceptions noted above, a fine example of protective requirements; our major concern, as I have indicated, is the absence of clear authority to require compliance. We shall transmit this concern directly to the President and the appropriate Congressional committees, since we appreciate the fact that it is not within your authority to respond to them.

Thank you for the opportunity to review and comment on the draft "Guidelines"; your staff should be complimented for a fine job.

Sincerely yours,



Kenneth J. Ryan, M.D.
Chairman

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SUBJECT: (Optional)

SSCI

OLC RECORD COPY

FROM:

EXTENSION

NO.

OLC 77-3957/a

DATE

7 October 1977

TO: (Officer designation, room number, and building)

DATE

OFFICER'S INITIALS

COMMENTS (Number each comment to show from whom to whom. Draw a line across column after each comment.)

RECEIVED

FORWARDED

1. SA-D/DCI/IC

Attached is an inquiry from Senator Inouye and a response which was coordinated with [redacted] IC Staff. The inquiry asked for guidelines now being prepared for protection of human subjects. The last sentence of the second paragraph states "the new draft is expected shortly and I will forward it to the Committee once it has been addressed by the NFIB". In addition, the incoming letter asked for comments on Dr. Ryan's letter to Walt Elder and Admiral Turner's response states he will forward comments to Senator Inouye after NFIB review. A follow-up letter must be sent to Senator Inouye enclosing draft and commenting on Ryan's letter to Elder. Will you please have such a draft response forwarded to me as soon as possible after the NFIB review and enclose a copy of the guidelines. Thank you very much.

FROM

Central Intelligence Agency
Washington, D.C. 20505

NO.

T 207784

DATE

7 Oct 77

TYPE OF MATERIAL

X

ENVELOPE(S)

PACKAGE(S)

OTHER

TO:

SA-D/DCI/IC
B-1000

Community Headquarters Building

LOG DATA

DATE AND TIME OF PICK-UP

COURIER'S INITIALS

ORIGINATING OFFICE LOG

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13.

14.

15.

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FORM 3-62

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TRANSMITTAL AND DOCUMENT RECEIPT
Approved For Release 2005/09/28 : CIA-RDP79M00983A001500050022-4

TO: Honorable Daniel K. Inouye, Chairman
Select Committee on Intelligence
United States Senate
Washington, D.C. 20510

FROM: Office of Legislative Counsel
Central Intelligence Agency
Room 7 D 35
Washington, D.C. 20505

THE DOCUMENTS LISTED HEREON ARE FORWARDED FOR:

INFORMATION	ACTION	<input checked="" type="checkbox"/> RETENTION	LOAN
CONTROL NUMBER	DOC. DATE	SUBJECT (Unclassified preferred)	CLASS.
	5 Oct 77	ltr to Chm. Inouye fr Adm. Turner re guidelines for Human Subject Research Within the Intelligence Community (R#9691)	U

Receipts

SSCI

77-0766/277

Entire pkg on

Drug guidelines

RECEIPT

SIGNATURE (acknowledging receipt of above documents)

Candace H. Hartley
DATE OF RECEIPT
6 Dec 1977

RETURN TO



OFFICE OF LEGISLATIVE COUNSEL
CENTRAL INTELLIGENCE AGENCY
ROOM 7 D 35
WASHINGTON, D.C. 20505

25X1

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SUBJECT: (Optional)

OLC RECORD COPY

FROM:

Assistant Legislative Counsel

EXTENSION

NO.

OLC 77-3957/a

DATE

4 October 1977

TO: (Officer designation, room number, and building)

DATE

OFFICER'S
INITIALS

COMMENTS (Number each comment to show from whom to whom. Draw a line across column after each comment.)

RECEIVED

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1. DDS&T/ORD

2. IC Staff

The Director's Executive Secretary did not like my letter and it was rewritten on a crash basis and was sent back to him without any chance for further coordination. If there are grievance errors in this, please let me know ASAP, otherwise, it will have to go as is. Thanks again for your help.

SSCI

77-0666/249

att
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3957/A